Volume 6 | Issue 1

October 2020

NYS-ACCP Insider

Albany College of Pharmacy and Health Sciences

ACPHS-SCCP Student Chapter Update

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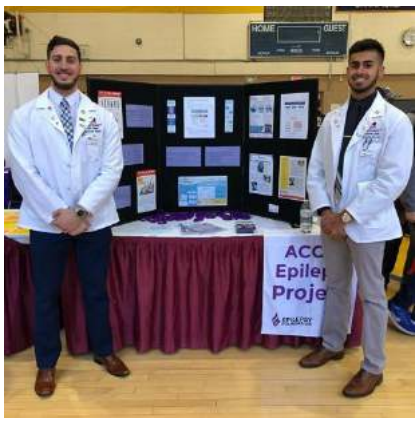
Albany College of Pharmacy and Health Sciences' (ACPHS) SCCP chapter's mission is to promote early involvement in the American College of Clinical Pharmacy (ACCP) as a national organization. Since our chapter was founded, students have been given the opportunity to develop and display clinical knowledge, hands on skills, and professionalism to prepare for future endeavours as pharmacy professionals. With the aid of our faculty advisors, Dr. Katherine Cabral and Dr. Michael Kane, ACPHS-SCCP focuses on providing networking, clinical experience, and direct patient care opportunities for our members.

With the onset of COVID-19 came the need to switch from large, in- person, community events to collaborative, virtual events. Nevertheless, so far this year, we have seen a substantial increase in attendance and participation in our annual events and patient care projects compared to previous years. We are continually trying to be creative, understanding, and engaging with our students and community throughout this pandemic.

Our Script Your Future (SYF) project, which emphasizes medication adherence, will be holding a virtual event "Adherence in Alzheimer's." This will focus on the role of healthcare professionals in aiding Alzheimer's patients with their care and medication adherence.



Our growing Epilepsy project, which advocates for the understanding of epilepsy, will host a virtual "Seizure 101 Trivia Night" event where our co-chairs will provide a presentation about epilepsy, seizure treatment and seizure first aid.

Our chapter's CaRE (Cardiovascular and Renal) screenings give members and students a unique opportunity for direct patient care. After completing training, volunteers measure blood glucose levels and blood pressure, calculate BMI, and counsel patients on interpretation of their results, as well as, their current pharmacologic and non-pharmacologic treatments. In the past year, we have provided screenings in senior housing, churches, YMCAs, Albany Community Health Day, and on Legislative Day at Albany's Capital Building. This year CaRE hopes to complete multiple in- person or virtual screenings in the community.

CaRE for KIDneys visits elementary schools in the Albany area to teach elementary aged children about diabetes and CV disease while promoting aerobic exercise and healthy diets. This year, we will team up with a local community center to teach about the importance of hand hygiene.

Members and students at ACPHS also benefit from attending any of our Clinical Pharmacy Challenges. We host six of these challenges each year and they include a variety of clinical topics, such as nephrology, neurology, Self-Care/OTC, and cardiology. Attendees compete in pairs and answer Kahoot! questions for prizes. Our CPC project hosted a virtual Neuro/Psych challenge this year and we are looking forward to their Self-Care/OTC challenge in the upcoming weeks.

Each of our patient care projects are hard at work planning and organizing events for this year as we continue to expose and educate students on the growing world of clinical pharmacy. We have a large following of active students that are eager to get involved and participate in our events. The push to virtual learning and participation has shown our perseverance and creativity in coming up with new event ideas, we look forward to seeing what our organization and future national members will do in the future.

Colin Duell, PharmD Candidate ACPHS Class of 2022

NYS ACCP Insider Executive Team Column: The E-Corner

Hello members!

On behalf of Kathryn Connor (President-Elect), Amanda Winans (Past-President), Bennett Doughty (Treasurer/Secretary), and myself, we welcome you to the first ever E-Corner of the NYS ACCP Insider Newsletter. Our aim with this new column, written by our executive officers, is to open up another means of communication with you on a monthly basis so we may keep you abreast of news and updates about chapter activity. Likewise, if you have questions for us that may be helpful for all

chapter members to know the answer to, we are happy to answer them in this column as well - please email questions to Amanda Engle Amanda.Engle@acphs.edu.

We hope that you will join us for the NYS ACCP Annual Meeting this year- virtually – on Friday November 6th. There is a stellar line up of CE planned for you, along with a virtual poster session, concurrent student programming, and several exciting announcements- namely, who the recipients of our Annual Peer Recognition Awards for Clinical Practitioner, Educator, and Researcher of the Year are, and who you voted in as our new President-Elect. CE will be pre-recorded and live-streamed with live speaker Q&A following their presentation to remain on schedule and minimize risk of technology glitches. This is an innovative approach to holding a virtual meeting that we look forward to sharing with you!

We are excited to present to you three *very* strong candidates for President-Elect this year. The two week voting window will begin on October 22nd and end on November 5th. Please look out for an email later in October with candidate bios and vision statements for your review prior to casting your vote.

On September 11th, NYS ACCP hosted Dr. Elsen Jacob and the Coalition for the Advancement of Pharmacy Practice at the quarterly NYS Pharmacy Conference Meeting. CAP was well received by the group, who was supportive and offered constructive feedback on historical barriers to moving forward similar legislative efforts. Please check out https://pharmacistcoalition.com/and join the movement! We urge you to consider your role in this landmark movement to achieve pharmacist provider status.

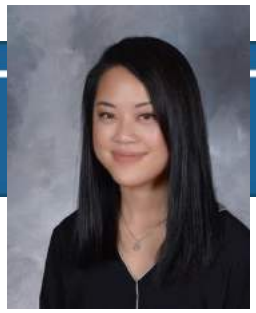
Please apply for the $3000 grant we sponsor to support research that improves drug use and/or advances clinical practice across NYS. Applications are due November 20th with recipient notification December 18th. Please reach out to Stephen Rappaport, Chair of the Research Grant Committee, to submit an application or for additional information.
Stephen_Rappaport@URMC.Rochester.edu

Thank you for reading our first ever E-Corner, and we hope you enjoy this issue of the student-led NYS ACCP Insider!

Best,

Amanda Engle, PharmD, BCPS
President, NYS-ACCP

Dapagliflozin Demonstrates Renal Protection: Results of the DAPA-CKD Study



By Felicia Le, PharmD Candidate, ACPHS Class of 2021

Sodium-glucose co-transporter 2 (SGLT2) inhibitors work by increasing urinary glucose excretion resulting in reduced glucose and hemoglobin A1c (HbA1c) levels in patients with type 2 diabetes mellitus (T2DM).[1] Results of cardiovascular outcome trials (CVOT) [2-4] have demonstrated the cardiorenal benefit of SGLT2 inhibitor therapy beyond glycemic control. Secondary endpoints of these CVOT trials have suggested the renal protection of these agents prompting the investigation of specific renal outcome studies.

CREDENCE was the first trial completed to directly assess the potential renal protection of SGLT2 inhibitors in patients with type 2 diabetes and CKD. Study results demonstrated that canagliflozin 100 mg/day reduced the risk of a composite renal endpoint (including doubling of serum creatinine, end stage renal disease (ESRD), or death due to renal or cardiovascular disease) by 30% compared to placebo.[5]

The recently published DAPA-CKD trial evaluated the effect of dapagliflozin in patients with chronic kidney disease (CKD), with or without type 2 diabetes.[1] This international, multicenter, randomized, double-blind, placebo-control trial evaluated dapagliflozin in CKD patients already receiving the standard of care of renal protection therapy. 4,304 patients were randomized to either placebo or dapagliflozin 10 mg given once daily. Inclusion criteria included adults ≥18 years old with or without diabetes, CKD with an estimated glomerular filtration rate (eGFR) of 25-75 mL/min/1.73m^2 and a urine albumin-to-creatinine ratio (UACR) of 200-5000 mg/g. A low eGFR and a high UACR are strong risk factors for renal and cardiovascular events. Patients were required to be stable and on the maximum tolerated labelled doses of an ACE inhibitor or ARB for at least four weeks before screening. Patients were excluded if they had type 1 diabetes, polycystic kidney disease, lupus nephritis or ANCA-associated vasculitis; if they were receiving cytotoxic or immunosuppressive therapy for renal disease; and if they had NYHA Class IV congestive heart failure, a cardiovascular event within 8 weeks prior to enrollment, coronary revascularization, or hepatic impairment. The primary study outcome was a composite of a sustained decline in eGFR of at least 50%, ESRD (defined as an eGFR <15 mL/min/1.73m2 or chronic dialysis treatment or receiving a renal transplant), or death from renal or cardiovascular causes. Secondary endpoints included time to the first occurrence of ≥50% sustained decline in eGFR or reaching ESRD or renal death, time to first occurrence of cardiovascular death or hospitalization for heart failure, and time to death from any cause.

Over a median of 2.4 years, a primary outcome event occurred in 9.2% in the dapagliflozin group compared to 14.5% for a hazard ratio (HR) of 0.61(95% CI, 0.51-0.72); the number needed to treat was 19. Benefit was seen in those with (HR = 0.64; 95% CI, 0.52-0.79) or without (HR = 0.50; 95% CI, 0.35-0.72) type 2 diabetes. All three secondary endpoints showed improvements as well, including a 44% reduction in worsening renal function or death from renal failure (95% CI, 0.45-0.68), a 31% reduction in all-cause mortality (95% CI, 0.53-0.88), and a 29% reduction in heart failure hospitalization or cardiovascular death (95% CI, 0.55-0.92). On October 2, 2020, the FDA granted breakthrough therapy designation for dapagliflozin for adults with chronic kidney disease with and without type 2 diabetes.[6]

The renal benefits of SGLT2 inhibitors are not explained by the modest reductions seen in HbA1c between treatment groups. Renal protective effects have been proposed to be due to activation of tubuloglomerular feedback, a decrease in intrarenal hypoxia, and suppression of anti-inflammatory and antifibrotic pathways.[7,8,9] Glomerular hyperfiltration is associated with a greater risk of microalbuminuria and a progressive decline in kidney function. SGLT2 inhibitors increase distal sodium delivery, resulting in restoration of tubuloglomerular feedback. Reduced sodium delivery to the macula densa suppresses tubuloglomerular feedback, causing afferent arteriole vasoconstriction which leads to decreased renal blood flow and hyperfiltration, and reduced albuminuria. The proximal tubule is where water, organic solutes and electrolytes are reabsorbed, and these processes are oxygen dependent. SGLT2 inhibitors reduce sodium and glucose reabsorption, leading to reduction in tubular workload and enhanced renal oxygenation, which improves tubular cell structural integrity and function. Inflammation, oxidative stress and fibrosis are also involved in initiation and progression of kidney disease. SGLT2 inhibitors have been associated with reduction in anti-inflammatory, antioxidant and antifibrotic markers.

In conclusion, the DAPA-CKD study is the first dedicated clinical trial to investigate the use of SGLT2 inhibitors in patients across multiple CKD stages with or without diabetes who are already

receiving standard of care, evidence-based renoprotective therapy. Dapagliflozin should be considered as a new standard of care for renal protection in patients with underlying nephropathy.

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Pharmacy Advocacy in Pandemic Times: Why, What, How?

By Elsen C. Jacob Pharm.D., BCPS, BCGP, CPPS

The COVID-19 pandemic has revealed that our public health system lacks the robust infrastructure necessary to provide high-quality, cost-effective and timely care. To assemble the scaffolding necessary to care for patients during this unprecedented pandemic, pharmacists in New York State (NYS) and around the nation have worked tirelessly to develop innovative strategies and labor alongside healthcare colleagues to ensure that patients and communities continue to receive high quality care. Even still, there remains a need for a permanent, robust foundation to support the healthcare of a nation facing a viral pandemic, an opioid epidemic, an aging population and mounting healthcare costs.[1] As members of a highly-trained, skilled and accessible discipline, pharmacists are well-positioned to deliver high-quality cost-effective care and address many of the unmet healthcare needs of our nation's communities.[2,1]

Why advocate now?

Historically, there has been a hesitancy to enact bold pharmacy practice legislation in NYS. The reasons for this include 1) a lack of the public's and legislators' awareness of pharmacists' training and skills 2) inaccurate perceptions of pharmacists in the press 3) reduced availability of pharmacoeconomic and human factors data demonstrating the value of pharmacists to patients and medical teams 4) sluggishness of the legislative process and 5) lack of unity amongst pharmacists practicing in varied arenas. However, the COVID-19 pandemic has led to a state of emergency, and legislators and the public are looking for solutions. As such, it is time to develop solutions and unify as a discipline in NYS to advance pharmacy practice and enhance patient care.[3] If pharmacists hesitate, we risk others outside of the profession defining our profession for us. In order to see systemic change, pharmacists and student pharmacists must view it as an obligation to pursue relentless advocacy efforts.

What are we advocating for?

Every pharmacist in NYS deserves to have the opportunity to practice at the top of their licenses. In NYS, there remains a gap in the training that pharmacists receive and what pharmacists are allowed to do per the law. Legislative changes will allow pharmacists in the state to 1) obtain fair compensation for cognitive services, not just for products and 2) advance our scope of practice.[1] These changes will allow for optimization of patients care, job satisfaction, opportunities for growth, reduced burn out, further interdisciplinary partnerships and appropriate remunerations.

While pharmacists in NYS provide care, we are not recognized as providers. Pharmacists deserve to be legally recognized as providers which includes fair compensation for cognitive services.[4] These services should include aspects of current practice such as counseling, consultation and testing. Also, advanced scope of practice would reflect practice in many states outside of NYS and can include access to patient information in all settings, and advanced pharmacist roles in management of smoking cessation, HIV-pre and post exposure prophylaxis, contraception and simple ailments, and administration of all adult vaccinations. Changes could also enable pharmacists to more directly address the opioid epidemic, and COVID-19 and future pandemics, and bridge the gap in shortage of health care providers in rural areas.[1]

How can we advocate?

Accurate portrayal of pharmacists

To witness real change in pharmacy practice, it is important that stakeholders including healthcare colleagues, patients, legislators and the public gain an accurate understanding of pharmacists' training, skills, and roles. Pharmacists must educate stakeholders through conversations, leveraging social media, and other outlets, and writing about pharmacy practice.

Legislation

It is important for pharmacists to learn about issues that impact practice, and to unify and advocate for change. Pharmacists could consider becoming involved in advocacy efforts through organizations at the local, state and national level, and in movements like the Coalition for the Advancement of Pharmacy Practice (pharmacistcoalition.com), a grassroots movement in NYS. Connecting with legislators, even if virtually, and sharing about your education role, hopes for the future, and desire for change is a strategic way to foster conversation and change.[3]

Training

Legislative changes to pharmacy practice have a lasting impact, and all pharmacists and student pharmacists can play a role in advancing the profession. Colleges of Pharmacy and training programs should consider incorporation of advocacy into the curriculum. Preceptors and faculty may consider

discussing advocacy and contacting legislators together with trainees. This will allow for the development of a larger network of advocates for the profession.[3]

Allies

While pharmacists need to lead the process of advocacy for the pharmacy profession, interdisciplinary collaboration and public support from our colleagues in healthcare is vital. It is important to educate our physician, physician assistant, nurse, nurse practitioner, and other colleagues of the training and skills that pharmacists bring, and the barriers to providing care that pharmacists face. In identifying colleagues who are willing to advocate on pharmacists' behalf and serve as champions for the profession, we will be well-positioned for legislative success.

The COVID-19 pandemic has allowed legislators and the public to become receptive to innovative solutions to care for patients, protect public health and lower healthcare costs. In NYS, we have the opportunity to unify our profession, and enhance our advocacy efforts to push for change in our profession. Through working to change the image of pharmacists, understanding issues, identify non-pharmacist champions, and push for legislative change, we may be able to gain compensation for services and increase our scope of practice to care for patient in conjunction with our colleagues. As members of the New York State Chapter of ACCP, let's get excited to amplify our efforts to see real changes happen in our state.

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Colchicine Use in ASCVD Patients for Prevention of CV Events

By Joanne Yeung, PharmD Candidate, ACPHS Class of 2021

Colchicine is indicated for prophylaxis and treatment of gout flares in adults and familial Mediterranean fever in children.[1] The primary mechanism of colchicine is tubulin disruption, leading to downregulation of multiple inflammatory pathways, as well as modulation of innate immunity.[2] The exact mechanism of colchicine in the inflammatory pathway is unknown but it's hypothesized to dampen chemotaxis and thus the release of inflammatory mediators. Colchicine also has a role in stabilizing atherosclerotic plaques, possibly due to a sprinkling of its anti-inflammatory abilities.

Colchicine was first shown to have potential benefits in the prevention of cardiovascular (CV) events in the Low-Dose Colchicine for Secondary Prevention of Cardiovascular Disease (LoDoCo) trial, published in 2013.[3] This study showed that colchicine 0.5 mg/day, in addition to standard preventative therapies (aspirin and high-dose statins), reduced the risk of acute coronary syndrome.

Subsequently, the Colchicine Cardiovascular Outcomes Trial (COLCOT) was conducted to look at CV outcomes and long term safety of colchicine in patients who recently had a myocardial infarction within 30 days of enrollment.[4] The trial concluded that a low dose of colchicine 0.5 mg/day led to lower rates of CV events (cardiac arrest, myocardial infarction, stroke) compared with placebo (composite HR=0.77, 95% CI=0.61-0.96). At about the same time, the Colchicine to Improve Cardiovascular Outcomes in Acute Coronary Syndrome (ACS) Patients [COPS], study was published; looking at the effects of colchicine 0.5 mg twice daily for 1 month followed by 0.5 mg/day in patients with ACS.[5] Conversely, this study showed no improvement in CV outcomes at 365 days when compared with placebo and in fact, showed an increased rate of all cause death and non-CV mortality compared to placebo.

Most recently, Colchicine in Patients with Chronic Coronary Disease (LoDoCo2) was published. It was a randomized-controlled, double-blind, event driven trial to follow up on LoDoCo.[6] A total of 5,522 patients were randomized to receive either 0.5 mg of colchicine once daily (n=2762) or placebo (n=2760). Patients were between 35 and 82 years of age and eligible if they had evidence of coronary disease on invasive coronary angiography or CT angiography or a coronary artery calcium score of at least 400 Agatston units. The patients were required to be clinically stable for at least 6 months prior to enrollment and were followed for an average of 28.6 months. All patients had similar baseline characteristics with 84.1% of patients in the colchicine group having prior ACS, 12% having history of atrial fibrillation and 83.3% having prior coronary revascularization. Exclusion criteria included patients that had moderate to severe renal impairment, severe heart failure, severe valvular heart disease or known side effects from colchicine.

The primary endpoint, a composite of CV death, MI, ischemic stroke or ischemia driven coronary revascularization, occurred less in colchicine group (6.8% vs 9.6%, HR=0.69; 95% CI=0.57-0.83; $p<0.001$).[6] This resulted in a 31% relative risk reduction in the primary endpoint with colchicine use. All-cause mortality (excluding CV related deaths) occurred more frequently in the colchicine group compared to placebo (0.7 vs 0.5 events per 100 person-years; HR=1.51; 95% CI=0.99-2.31). Incidence of adverse events were similar in both groups. Not surprisingly, the incidence of gout occurred less frequently in the colchicine group compared with placebo (1.4% vs. 3.4%). Although not statistically significant, the most common adverse events reported were gastrointestinal related (nausea, diarrhea) which was also consistent across the LoDoCo2, COLCOT and COPS trials. Pneumonia was a rare but serious adverse event that occurred more frequently in the colchicine group, however it was not statistically significant nor was the need for hospitalization for infection. It was postulated that this was due to immune modulating effects of colchicine, which increases risk for infection. The COLCOT trial also found a higher incidence of pneumonia in the colchicine group compared to placebo (0.9% vs 0.4%, $P = 0.03$).[4] The COPS trial found a possible correlation with colchicine and infection/pneumonia but did not evaluate it during the trial.[5] LoDoCo did not evaluate for infection related adverse events.[3]

Limitations of the LoDoCo2 trial include smaller ratio of women (16.5% in colchicine vs 14.1% in placebo) to men and thus not able to have an equal distribution in patient population.[6] Interactions between low-dose colchicine and high dose statins were not assessed and this may be significant due to the majority of the study population on baseline statins (93.9% in colchicine vs 94% in placebo). This may be significant because myalgia was an adverse effect (21.2% in colchicine group vs 18.5% in placebo group) that was evaluated. Blood pressure, lipid levels, C-reactive protein or other inflammatory markers were not collected at baseline or the duration of the trial.

In conclusion, low-dose colchicine 0.5 mg/day, was shown to have potential benefits in prevention of CV events (cardiovascular death, ischemic stroke, ischemia-driven coronary revascularization) in patients who have had a past ACS event. However, the LoDoCo2 trial did not show a statistically significant reduction in MI (p=0.01).[6] Due to the limitations of the trial, larger studies are recommended to provide further insight of long term effects, possible adverse reactions, as well as interactions with common drug regimens pertinent to this patient population. The postulated anti-inflammatory mechanism of colchicine in preventing plaque progression as well as improvement in plaque healing process is promising and provides a novel option for prevention of future CV events.

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Pralsetinib (Gavreto) for RET-Fusion Positive Non-Small Cell Lung Cancer

By David Roberts, PharmD Candidate, Class of 2021

In the United States, more people die from lung cancer than any other type of cancer, with an estimated 145,849 deaths in 2017.[1] Non-small cell lung cancer (NSCLC) accounts for approximately 85% of lung cancer cases and has several treatment modalities currently available. Deaths from NSCLC have been declining in recent years, largely due to the development of immunotherapies and targeted therapies. Targeted therapies work on molecular mutations that drive the growth of NSCLC. Mutations that occur in BRAF V600E, ROS1, EML4-ALK, EGFR, and KRAS all currently have FDA-approved targeted therapies. Another targetable molecular mutation has recently gained an FDA-approved specific therapy - mutation of the RET gene. The RET (rearranged during transfection) proto-oncogene is a receptor tyrosine kinase involved in cell proliferation, cell migration, and cell differentiation. In approximately 1-2% of NSCLC cases, RET has undergone a fusion or rearrangement mutation that results in hyperactivation of downstream signaling pathways and uncontrolled cell proliferation.[2]

On September 4, 2020, the FDA approved pralsetinib (Gavreto®) for the treatment of adults with metastatic RET fusion-positive NSCLC as detected by an FDA-approved test. The Oncomine Dx Target (ODxT) Test (Life Technologies Corporation) was granted premarket approval shortly after

pralsetinib on September 8th as a companion diagnostic test.[3] Pralsetinib, just the second in its class after selpercatinib (Retevmo®) was approved in May, is a tyrosine kinase inhibitor of RET that exhibits anti-tumor activity in cells with oncogenic RET fusions.[2] The new drug was granted accelerated approval by the FDA, based on data from the phase I/II ARROW study.[4] The efficacy of pralsetinib for RET fusion positive NSCLC was evaluated in 87 patients previously treated with platinum chemotherapy. Pralsetinib demonstrated an overall response rate (ORR) of 57% (95% CI: 46%, 68%) with 80% of these patients having a response lasting 6 months or longer. In 27 treatment naïve patients, pralsetinib demonstrated an ORR of 70% (95% CI: 50%, 86%) with 58% of these patients having a response that lasted 6 months or longer.[5] Overall response was defined as any complete or partial decrease in tumor size. These preliminary results indicate that pralsetinib may be a dependable option for patients who have previously had limited treatment options, but continued approval of the drug is dependent upon confirmatory trials that verify the drug's clinical benefit.[4] The most common adverse effects of pralsetinib (≥25%) are fatigue, constipation, musculoskeletal pain, and hypertension.[2] The National Comprehensive Cancer Network (NCCN) recommends pralsetinib as a preferred first line option and subsequent option in patients with a known RET fusion mutation in metastatic NSCLC.[6] When prescribing pralsetinib, clinicians should note there are several dose adjustments based on the incidence of certain adverse reactions (such as interstitial lung disease and hypertension), and when used concomitantly with strong CYP3A inhibitors and inducers (such as itraconazole and rifampin). There are also several parameters that should be monitored in patients taking pralsetinib, including blood pressure, AST, ALT, signs of infection, bleeding, and pneumonitis, as well as hemorrhage, hepatotoxicity, and impaired wound healing.[2] As a once daily oral therapy, pralsetinib serves as a promising new option for a subset of metastatic NSCLC patients, whose previous options were limited mainly to radiation and IV chemotherapy.

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